



Department of General Services  
Procurement Division  
707 Third Street, 2<sup>nd</sup> Floor  
West Sacramento, CA 95605-2811

State of California  
**CONTRACT NOTIFICATION**  
**Revision 1**  
**For State Departments**  
**And Local Health Departments**  
**Participating in the Anti-Viral Supply**  
**Program**

## State Contracts

Contract Number	Supplier	Description	Contract Term
1-06-65-60	Roche Laboratories Inc	Tamiflu® pandemic Influenza Supply	6/27/2006 through 6/28/2008
1-07-65-61	GlaxoSmithKline	Relenza® pandemic influenza supply	Through 5/31/2008

## Federal Contracts

Contract Number	Supplier	Description	Contract Term
HHS0100200600015I and modifications 1, 2 and 3	Roche Laboratories Inc	Tamiflu® pandemic Influenza Supply	Through 6/29/2008
HHS0100200600016 and modification #1I	GlaxoSmithKline	Relenza® pandemic influenza supply	Through 7/14/2008

\_\_\_\_\_  
**GREGORY DOE, Pharmaceutical Manager**

Effective Date: \_\_\_\_\_

**STATE OF CALIFORNIA  
STATEWIDE CONTRACTS 1-06-65-60; 1-07-65-61  
ANTI-VIRAL SUPPLY PROGRAM  
CONTRACT NOTIFICATION**

**1) SCOPE**

The State of California, Department of General Services (DGS) awarded statewide Master Purchase Agreements on behalf of the California Department of Health to Roche Laboratories Inc for Tamiflu® and to GlaxoSmithKline for Relenza® to provide antiviral countermeasures to respond to an influenza pandemic.

- a) The Anti-Viral Supply Program is available for use by State Departments and all of the State of California Local Health Departments (LHD) that meet requirements for pharmaceutical distribution.

Statutory authorities related to this notification include:

- i) Government Code Section 14977.1 (a) and (b) enabling the DGS to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multi source drugs, and exempting said contracts from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.
- ii) Public Contract Code Section 10298 enabling DGS to make its services available, upon the terms and conditions agreed to, to any city, county, city and county, district, or other local governmental body or corporation empowered to expend public funds for the acquisition of goods, information technology, or services for assisting the local department in acquisitions conducted pursuant to Chapter 2 (commencing with Section 10290), Chapter 3 (commencing with Section 12100), and Chapter 3.6 (commencing with Section 12125).
- iii) Health and Safety Code Section 101185 defining a "local health department" to mean any one of the following public health administrative organizations:
  - (1) A local health department serving one or more counties that shall provide services to all cities whose population is less than 50,000 in addition to the unincorporated territory of the county or counties
  - (2) A county health department that does not serve all of the cities of less than 50,000 population, but that has the provisional approval of the department, in accordance with Section 101225.
  - (3) The health department of a city of 50,000 or greater population, except that the governing body of the city by resolution may declare its intention to be included under the jurisdiction of the county health department, as provided by existing statutes.
  - (4) The local health department of any county that had under its jurisdiction on September 19, 1947, a population in excess of 1,000,000 or the local health department of any city and county.

- b) Any **Local Health Department (LHD)** desiring to participate shall:

- i) Sign a "Memorandum of Understanding-Anti-Viral Supply Program", and submit four (4) signed originals to CDPH. One executed original will be returned to the originator after signature by the California Department of Public Health (CDPH) and the DGS.
- ii) Submit payment payable to the supplier through the CDPH within five (5) days of receipt of an invoice.
- iii) Submit to the same requirements as do State Departments.
- iv) Have no authority to amend, modify or change any condition of the state and federal contracts listed on page 1. Authorization to permit a LHD to participate in this contract shall come through the State's Contract Manager.

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- c) Any State Departments desiring to participate shall:
- i) Sign a "Memorandum of Understanding-Anti-Viral Supply Program", and submit four (4) signed originals to CDPH. One executed original will be returned to the originator after signature by CDPH and the DGS.
  - ii) Submit Purchase Estimates to the CDPH.
  - iii) Have no authority to amend, modify or change any condition of the state and federal contracts listed on Page 1. Authorization to permit a State Department to participate in this contract shall come through the State's Contract Manager.
- d) State of California Departments and Local Agencies shall acquire, keep and maintain and provide with purchase estimate/order request at the time of submittal a copy of:
- i) DEA registration and  
  
A License (as clinic or pharmacy) by either the State Board of Pharmacy or license as a health care provider by The Dept. of Public Health.
- e) Orders must be shipped to the address specified on the DEA registration. Orders must be provided by the entity specified on the DEA registration.
- f) State Departments submitting purchase estimates (Form 66) must adhere to all applicable state laws, regulations, policies, best practices, and purchasing authority requirements, e.g. California Codes, Code of Regulations, State Administrative Manual, Management Memos, and State Contract Manual, Volume 2.
- g) LHD and State Departments must adhere to the requirements of the federal and state contracts listed on page 1, including but not limited to the following:
- i) HHS0100200600015I, HHS010020060016I, Section H2, "Placing and Processing Orders."
  - ii) HHS10020060015I, HHS010020060016I, Section H3, "Restrictions on Use of Product." "Product is intended to be dispensed once a Pandemic Alert Period (Phases, 3, 4, and 5) and Pandemic Period (Phase 6) is declared in accordance with the November 2205 WHO Global Influenza Preparedness Plan. Federal and/or state pandemic influenza-specific public health emergency declarations will also allow release of product under this contract. Use of product for any other purpose, including inter-pandemic use, requires approval of the Federal Contracting Officer, who will act only after receiving proper Department approval. The Government agrees that the product delivered under this contract will not be administered for use in humans, unless the Secretary executes a declaration in accordance with section 319F-3(b) of the Public Health Service Act that . . . (anti-viral supply program products are) a covered countermeasure to which section 319F-3(a) applies subject to the terms and conditions of the declaration."
  - iii) HHS0100200600015I, HHS0100200600016I, Section H, "Reporting Matters Involving Fraud, Waste and Abuse" "Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in National Institutes of Health (NIH) funded programs is encouraged to report such matters to the Health and Human Services (HHS) Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially." The e-mail address is [Htips@os.dhhs.gov](mailto:Htips@os.dhhs.gov) and the mailing address is:

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Office of Inspector General  
Department of Health and Human Services  
TIPS HOTLINE  
P.O. Box 23489  
Washington, D.C. 20026

- iv) HHS0100200600015I, HHS010020060016I Section I.7 52.216-18 "Ordering (Oct. 1995)".
- v) HHS0100200600015I, HHS010020060016I Section I.8, 52.216-19, "Order Limitations (OCT 1995)."
- vi) HHS0100200600015I, HHS010020060016I Section I.9 52.216-22 "Indefinite Quantity (OCT 1995)."
- vii) HHS0100200600015I, HHS010020060016I Section I.12, 52.249-14, "Excusable Delays (APR 1984)."

**2) STATE OF CALIFORNIA, PROCUREMENT DIVISION, CONTACTS ARE LISTED IN "KEY CONTACTS" AT THE END OF THIS NOTIFICATION.**

**3) CONTRACT USAGE/RULES**

LHD and State Department use of this contract is optional. While the State makes these contracts available to the LHD, each LHD should determine whether this contract is consistent with its procurement policies and regulations. Part 1e of the above requirements and restrictions are not applicable to LHD.

**4) MANDATORY ORDERING REQUIREMENT**

Contracts 1-06-65-60 and 1-07-65-61 require that the CDPH authorize orders and that the State Contracting Officer of the DGS place all orders. LHD and State Departments are instructed to contact Dr. Tom Ahrens, the CDPH Entity Authorizing Official (EAO) to discuss order. State agencies shall submit purchase requests to Dr. Ahrens of CDPH with items listed in 1d. Dr. Ahrens will review and authorize the purchase requests. CDPH will submit purchase estimates for authorized orders to DGS for logging and placement. The DGS will submit CDPH authorized orders to the HHS for authorization and submit HHS authorized orders to the supplier. The order will be delivered to CDPH and reshipped to the LHD. Only orders that have been authorized by the CDPH Entity Authorizing Official (EAO) and placed by the DGS Ordering Official will be eligible for the pricing specified in this contract. Please refer to "Anti-Viral Supply Program Order Process" Chart on page 9.

**5) PRODUCT PAYMENT, ADMINISTRATIVE FEE BILLING, SHIPPING REIMBURSEMENT**

State Departments and LHD will submit payment payable to supplier through CDPH for processing. CDPH will forward product payment to supplier. CDPH will bill the State department/LHD for the DGS administrative fee and CDPH shipping costs as described in "Memorandum of Understanding-Anti-Viral Supply".

**DGS ADMINISTRATIVE FEE.**

The DGS will bill CDPH an administrative fee for each purchase by state departments and local health departments. CDPH will bill the State department/LHD for the DGS administrative fee and CDPH shipping costs as described in "Memorandum of Understanding – Anti-Viral Supply". The administrative fee should NOT be included in the order total, nor remitted before an invoice is received from CDPH. (You may click on "DGS Price Book" at: <http://www.ofs.dgs.ca.gov/Price+Book/P/Purchasing.htm> for current fees.)

**6) CONTRACT MANAGEMENT**

The federal government has assigned DGS and CDPH contact personnel below as the single points of contact for problem resolution and related contract issues.

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**State Contract Manager, designated as State's Ordering Official:** Contact information is listed in "Key Contacts" on page 7 of this document.

**State's Entity Authorizing Official:** Contact information is listed in "Key Contacts" on page 7 of this document.

**7) PURCHASE ORDER EXECUTION**

State departments shall submit a Purchase Estimate (Std. 66) for CDPH review and DGS order placement as specified Section 4. LHDs shall (in lieu of the State's Purchase Estimate Std. 66) submit their own purchase order document for CDPH review and DGS placement as specified in Section 4. An electronic version of the Std.66 is available at the Office of State Publishing web site: <http://www.dgs.ca.gov/osp> (select Standard Forms", then select "STD. Forms Pilot Home" ).

Prior to submitting an order, State departments/LHD must sign a Memorandum of Understanding- Anti-Viral Supply. It is not necessary to provide this documentation to DGS when submitting a copy of the Std. 66. The name of the entity placing the order must be the same name as that of the entity signing the Memorandum of Understanding-Anti-Viral Supply.

In accordance with the referenced federal contracts for anti-viral supply, each order shall contain:

- Name of supply being ordered
- Contact Information: Name of Entity's ordering officer, address, telephone number and fax number
- Ship to Location: Name of contact, delivery address, telephone number and fax number
- Invoice contact, delivery address, telephone number and fax number.
- Quantity (courses of therapy to be purchased); and unit price

**8) ORDER ACKNOWLEDGEMENT/CONFIRMATION**

DGS will confirm receipt of request. CDPH will confirm whether order is authorized. DGS will confirm:

- transmittal of order to HHS contracting officer,
- whether order is authorized,
- and order placement date.

**9) CONTRACT PRICING**

The total amount of each treatment course is:

\$19.24 for Tamiflu®, 75 mg (oseltamivir phosphate) Capsules packaged as 10 capsules per bottle (NDC 0004-0800-06)

\$12.98 for Tamiflu®; 45 mg (oseltamivir phosphate) Capsules packaged as 10 capsules per bottle (NDC: 0004-0801-06)

\$8.66 for Tamiflu®; 30 mg (oseltamivir phosphate) Capsules packaged as 10 capsules per bottle (NDC: 0004-0802-06)

The total amount of each treatment course is \$21.72 for Relenza®, (zanamivir for inhalation) packaged as 5 Relenza Rotadisks® each containing four-5mg blisters and one Diskhaler inhalation device per box (NDC #0173-0681-22).

Supply	NDC	Packing	Unsubsidized Price	Subsidized Price
Tamiflu®	0004-0800-06	75 mg capsules packaged as 10 capsules per bottle	\$19.24/bottle	\$14.43
Tamiflu®	0004-0801-06	45 mg capsules packed 10 capsules per bottle	\$12.98	\$9.74
Tamiflu(4)	0004-0802-06	30 mg capsules packed 10 capsules per bottle	\$8.66	\$6.50
Relenza®	0173-0681-22	5 Relenza Rotadisks® each containing four-5mg blisters and one Diskhaler inhalation device per box.	\$21.72/box	\$16.29

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**10) FOB POINT**

FOB point is FOB destination for shipment from the Contractor to the CDPH to the CDPH delivery site in accordance with federal contracts HHS0100200600015I and HHS010020060016I. FOB point is FOB Shipping point for shipment from CDPH to State Department or Local Health Department's DEA registration address.

**11) DELIVERY**

**Delivery will be made as specified in the federal contracts listed on page 1 (page 29 for contract HHS0100200600015I, page 19 of contract HHS0100200600016I).**

Delivery will be made as specified in Attachment 3 of federal contracts HHS0100200600015I and HHS010020060016I, point 9 Note. Orders will be filled as received by the supplier. Orders placed outside the terms of this contract will be filled as received chronologically.

**12) MINIMUM ORDER**

The only units of issue accepted by this order are specified in Section 9 of this notification.

A minimum dollar amount for each order may be specified in the federal contract.

**13) REFUSAL TO ACCEPT ORDERS**

Supplier shall only accept orders placed by the State's Ordering Official.

**14) RECEIPT PROCEDURES**

Pharmaceutical receipts must be acknowledged by the ordering facility pharmacist or an authorized designee.

**15) INVOICES**

Items will be invoiced by Supplier to CDPH against the contract release number and contain the following:

- Federal Contract Number
- Description of goods or services,
- Quantity purchased
- Unit price
- Total Amount
- Charges for freight or express shipments other than F.O.B. destination
- Invoice Date
- Invoice Number

**16) PAYMENT**

Payment Terms: State Departments/LHD will pay supplier invoices within five (5) days of receipt of the invoice from CDPH. **Payment to the Supplier must be processed through CDPH and not sent directly to the supplier.** Any late charges due to delay on the part of the State Department/LHD will be billed to that department by CDPH. The DGS administrative fee and shipping costs will be billed separately by and is payable to CDPH.

a) Payee Data Record (Std. 204)

Contact State's Ordering Official (listed on Page 8) for a copy of supplier's payee data record (Std. 204)

**17) PRODUCT RECALLS**

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Manufacturers will notify the State's Authorizing Official of any recalls as instructed in the manufacturers' notification.

18) **PRODUCT SHELF-LIFE**

The referenced federal contracts specify that the supplier will ship newly manufactured and/or have full shelf life as determined by FDA for the antiviral drugs being shipped. This is subject to the approval of FDA.

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**KEY CONTACTS**

CDPH			DGS	
Entity Authorizing Official (EAO)	Tom Ahrens, Pharm.D.		State Ordering Officer (OO)	Loretta Maddux
Address:	CDPH Emergency Preparedness Office P.O. Box 997377 MS 7002 Sacramento, CA 95899-7377		Address:	DGS 707 Third Street, 2 <sup>nd</sup> Floor, West Sacramento, CA 95605
Telephone	(916) 650-6438		Telephone:	(916) 375-4926
Facsimile:	9916) 650-6420		Facsimile:	(916) 375-4490
E-mail:	<a href="mailto:CDPHantiviraldrugpro@cdph.ca.gov">CDPHantiviraldrugpro@cdph.ca.gov</a>		E-mail	<a href="mailto:Loretta.Maddux@dgs.ca.gov">Loretta.Maddux@dgs.ca.gov</a>



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# Anti-Viral Supply Program Order Process

12/03/2007

